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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,324	01/13/1999	YUKOH HIEI	760-262P	7108

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

18

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/229,324

Applicant(s)

HIEI ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 14 February 2003, paper number 15, and of a certified English translation of the Japanese priority document, 204464/92, filed 7/07/92.
2. Applicant has cancelled claims 1-16, amended claim 17, and added new claims 18-34. Claims 17-34 are pending, and are examined in the instant action.
3. Claim 17 has been rejoined to claims 1-16, now cancelled, and newly added claims 18-34.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Substitute Specification***

6. The Office acknowledges receipt of Applicant's Substitution Specification, paper no. 17, and marked-up copy of the Substitution Specification. However, the Substitution Specification has not been entered, because the substitute specification needs to be accompanied by a statement that no new matter has been added.

### ***Claim Rejections - 35 USC § 112, second paragraph***

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7. Claims 17-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 17,

- What does “callus-deriving” mean? Does the medium derive from callus?
- Where did “the foreign gene” of “selecting a tissue in which a foreign gene” come from? A statement regarding providing a “foreign gene” needs to be present earlier in the sequence of steps, otherwise an essential element is missing from the steps.
- “gene” is unclear because “gene” implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. The recitation of a specific and defined gene, for example, the *Agrobacterium virA* gene, is definite.

However, “gene” as in “a foreign gene” is unclear.

In claim 18, and all claims dependent thereon, (i), is unclear because what the period “for a period of 1 to 6 days” refers to is not clear—does this refer to “culturing” or “induces”? Furthermore, this claim needs to have a step allowing the polynucleotide of interest to be transferred to the plant tissue. Without this step the claim is missing an essential step.

In claims 18 and 31, “bacteria that in turn comprise” is unclear. What does “in turn” mean? Suggested language is “wherein said bacteria comprises”.

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In claim 20, what does "immature tissue" mean? Is this tissue of an immature structure? Such as an "immature seed" or "immature flower". This is not an art-recognized term and is not defined in the specification.

In claim 22, what is a "super binary vector"?

In claim 27, "dedifferentiation inducing medium" lacks antecedent basis. The two recitations of "a" should be changed to "the", for clarity.

In claim 28, "normal plant" is unclear. What is a "normal plant"?

In claim 29, "the culture" lacks antecedent basis.

In claim 31 (i), "tissue of a period of 1 to 6 days" is unclear. What does this mean?

Clarification and/or correction are required.

***Claim Rejections - 35 USC § 112, first paragraph***

8. Claim 29 (previous claim 12) is rejected under 35 U.S.C. 112, first paragraph, because the specification lacks sufficient evidence that the claimed biological material (pTOK162) is either 1) reproducible, 2) known and readily available to the public, or 3) deposited in compliance with 37 C.F.R. 1.801-1.809. If the claimed biological material were deposited under the provisions of the Budapest Treaty, Applicant must provide a declaration stating that the claimed biological material was made under the provisions of the Budapest Treaty in compliance with 37 CFR 1.801-1.809, and that all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of the patent. Applicant's

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attention is directed to 37 C.F.R. §§ 1.801-1.809, M.P.E.P. §§ 2402-2411.05 and In re Lundak, 773 F.2d. 1216, 227 U.S.P.Q. 90 (Fed. Cir. 1985) for further information concerning the Rules and Regulations for Deposit of Biological Materials for Patent Purposes.

Applicant traverses, stating primarily that they submit Exhibit 1, T. Komari, Plant Cell Reports, 9, 303-306 (1990), which provides a restriction map of plasmid pTOK162 and a description of how that plasmid was made from previously described materials, and assert that one of ordinary skill in the art could readily reproduce this plasmid.

Applicant's traversal has been considered and is unpersuasive because the cited document gives some physical description of the plasmid but does not provide the nucleic acid sequence. Therefore, one of ordinary skill in the art would not be able to construct an identical plasmid. Also Exhibit 1 was not provided with the Amendment.

Accordingly the rejection is maintained.

9. Claims 18-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejected subject matter is "dedifferentiating". Applicant is invited to point out the page and line number in the specification where "dedifferentiating" can be found. Absent such support, Applicant is required to cancel the new matter in response to this Office Action.

***Claim Rejections - 35 USC § 102***

10. Claims 18-23, 25, 28, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Gould et al, Plant Physiol. (1991) 95, 426-434.

Gould teaches a method of transforming Zea mays comprising culturing shoot apices from germinating seedlings or embryos cultured (p427 1<sup>st</sup> column, final ¶) for 1-3 days followed by inoculation with Agrobacteria (p 427, final 3 ¶, and p 428, 1<sup>st</sup> two ¶ ¶), resulting in transformed Zea mays tissue (p 430, Table I, page 431, Table II), Agrobacterium A281 (p 427, 2<sup>nd</sup> ¶), immature embryos (p429, 2<sup>nd</sup> column-1<sup>st</sup> ¶), transgenic maize plants bearing  $\beta$ -Glucuronidase coding sequence (p 430, Table I, page 431, Table II). Gould also teaches the virB and VirG genes of Agrobacterium A281 (p427, 2<sup>nd</sup> ¶)

Accordingly, Gould anticipates the claimed invention.

Applicant traverses, stating primarily that Gould nor Graves disclose placing a plant tissue on a dedifferentiated-inducing medium, so that a dedifferentiating or dedifferentiated tissue is obtained that is contacted with Agrobacterium.

Applicant's traversal has been considered and is unpersuasive because a dedifferentiating medium can be virtually any culture medium. "[Dedifferentiation] is frequently observed when differentiated cells are explanted and grown in cell culture",

see Rieger, et. al., Glossary of Genetics and Cytogenetics, 1976, Springer-Verlag, New York, see page 139. Therefore the medium of Gould and of Graves is a dedifferentiation-inducing medium.

11. Claims 18-20, 23 and 25, are rejected under 35 U.S.C. 102(b) as being anticipated by Graves et al, Plant Molecular Biology (1986) 7, 43-50. Graves teaches Agrobacterium transformation of Zea mays germinating seedlings cultured for 4 days followed by inoculation with Agrobacteria (p 44, 1<sup>st</sup> column last paragraph, continuing to 2<sup>nd</sup> column). Accordingly, Graves anticipates the claimed invention.

Applicant traverses, stating primarily that Gould nor Graves disclose placing a plant tissue on a dedifferentiated-inducing medium, so that a dedifferentiating or dedifferentiated tissue is obtained that is contacted with Agrobacterium.

Applicant's traversal has been considered and is unpersuasive because a dedifferentiating medium can be virtually any culture medium. "[Dedifferentiation] is frequently observed when differentiated cells are explanted and grown in cell culture", see Rieger, et. al., Glossary of Genetics and Cytogenetics, 1976, Springer-Verlag, New York, see page 139. Therefore the medium of Gould and of Graves is a dedifferentiation-inducing medium.

12. Claims 18-25, 27-28, and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al (US 6,215,051, effective filing date 4 November 1992).



Yu teaches a method of transforming rice (Abstract, claims 1 and 8) by preculturing immature embryos for 2 days on dedifferentiation medium (col 17, lines 1-15), infecting precultured embryos with Agrobacterium A281 (col 16, lines 16-32) two days later, maintaining transformed tissue on differentiation inducing medium and selecting transformed tissue (col 17, lines 35-67), and transgenic rice plants (c 26, Table 3) bearing the DNA of interest. Accordingly, Yu anticipates the claimed invention.

Applicant traverses, stating primarily that Yu do not disclose placing a plant tissue on a dedifferentiated-inducing medium, so that a dedifferentiating or dedifferentiated tissue is obtained that is contacted with Agrobacterium.

Applicant's traversal has been considered and is unpersuasive because a dedifferentiating medium can be virtually any culture medium. "[Dedifferentiation] is frequently observed when differentiated cells are explanted and grown in cell culture", see Rieger, et. al., Glossary of Genetics and Cytogenetics, 1976, Springer-Verlag, New York, see page 139. Therefore the medium of Yu is a dedifferentiation-inducing medium.

Applicant traverses, stating primarily that Yu et. al. was filed in the time period between the filing of the Japanese priority application and the U.S. filing date of the present application. Applicants provide hereto a verified English translation of the priority document, which obviates the instant rejection.

Applicant's traversal has been considered and is unpersuasive because claims 18-34 have benefit of the filing date of 25 June, 1996, the date of filing the continuation in part of the parent U.S. application. The limitation "a period of 1 to 6 days" is not present in the parent case (see US 5,591,616), and this limitation appears in the instant case. Rather, US 5,591,616 recites, "for not less than 7 days" .

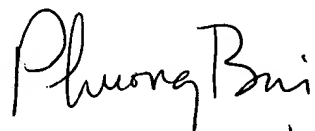
**Remarks**

14. No claim is allowed.
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner  
Art Unit 1638  
June 2, 2003

  
PHUONG T. BUI  
PRIMARY EXAMINER 6/2/03